

U.S. Serial No. 09/888,920

Amendment to Office Action dated December 15, 2004

**Remarks**

Claims 27 and 41 have been amended and new claim 46 has been added. Claims 30-34 and 40 remain withdrawn. Support for the amendments and new claim can be found in the specification, claims, and drawings as originally filed. No new matter has been added.

**Rejection under 35 U.S.C. § 102 (b)**

Claims 27-29, 37, 38, and 41-45 are rejected as being anticipated by Long et al. (US 4,632,488). Applicants respectfully traverse the rejection. Independent claims 27 and 41, as amended, recite a catheter tube hub having a lumen extending through a strain relief and connector, the lumen having a substantially fixed diameter along its length. Long et al. disclose a strain relief with integral electrical cord clamping component. See column 4, lines 43-48 and FIGS. 1, 5, 11A and 11B. Long et al. disclose "electrical cord clamping component 26 is integrally formed with bushing 24 and strain relief component 22 and includes a helical spring-like element 80...spring-like element 80 has a plurality of helical turns...the helical turns circumscribe a bore 84 disposed co-axially with bore 24 and bore 35." See column 8, lines 12-22 and FIG. 3. Long et al. teach that in order to clamp an electrical cord within the sleeve, the bushing is axially rotated "and as a result, the bore 84 (FIG. 3) defined by the inner surface of the helical spring-like section 80 decreases and such section 80 thereby tightens around the outer portion of the electrical cord 35 as shown in FIG. 11B" and that "helical spring-like section 80 becomes radially compressed" by rotating the bushing. See column 11, lines 1-8 and 15-17.

Long et al. thus teach a strain relief and electrical cord clamping device in which a bore or lumen extends from the strain relief through a bushing and clamping component, with the diameter of the lumen in the clamping component being reduced by turning the bushing to tighten around or clamp the electrical cord. Long et al. teach the lumen in the clamping region as radially compressing and expanding to clamp and un-clamp around the electrical cord as the bushing is rotated counterclockwise and clockwise, respectively. See column 11, lines 14-17 and FIGS. 11A-11C. The diameter of the lumen through the catheter tube hub instantly claimed is fixed, that is, the diameter is set when the hub is manufactured and does not substantially change during use. Long et al.'s strain relief

U.S. Serial No. 09/888,920

Amendment to Office Action dated December 15, 2004

sleeve with an expanding and contracting lumen diameter is thus distinguished from the instant claims.

Additionally, there is no motivation for one of ordinary skill in the art to modify the sleeve of Long et al. to have a substantially fixed diameter lumen because the sleeve of Long et al. is specifically designed to contract and expand to clamp and un-clamp an electrical cord within the sleeve. Modifying the sleeve of Long et al. to have a fixed diameter lumen would render the sleeve unsuitable for its intended purpose as it would no longer be capable of selectively tightening around and releasing the electrical cord. Long et al. fail to teach each and every element of independent claims 27 and 41 and the claims dependent thereon. Withdrawal of the rejection is respectfully requested.

#### **Rejection under 35 U.S.C. § 103**

Claims 27, 28, 38, and 41-43 are rejected as being unpatentable over Davila (US 5,466,230) in view of Klump, Jr. (US 2,724,736). Davila is asserted as disclosing a catheter tube hub having a lumen, proximal and distal portions, a helical wall with bends separated by spaces, where the proximal portion of the hub is thicker than the distal portion. The Examiner acknowledges that Davila fails to teach the spaces between the helical wall extending through to the lumen that extends through the hub or a hub made of nylon. Klump is asserted as teaching a strain relief distal portion with a helical wall with spaces extending through to the hub lumen and the use of nylon. The Examiner asserts that it would have been obvious to use the teachings of Klump in the hub of Davila in order to prevent the strain relief spring from breaking down the strain relief section. Applicants respectfully traverse the rejection.

Independent claim 27, as amended, recites an integral catheter tube hub having a lumen defined by a lumen wall extending from a distal end of the hub to a proximal end of the hub, with the lumen wall in the strain relief portion including a generally helical wall. Independent claim 41, as amended, recites a unitary catheter tube hub with a generally helical wall defining a lumen, where the helical wall of the strain relief transitions into a lumen wall of the connector. Davila discloses a three part catheter sheath introducer in which a separate hub, coil spring and sheath are connected to form a lumen extending from the sheath through the coil spring and hub. See FIG. 3 and column

U.S. Serial No. 09/888,920

Amendment to Office Action dated December 15, 2004

3, lines 16-19. The lumen wall in Davila is thus made up of the inner surface of the sheath in the distal portion and the inner surface of the hub in the proximal portion. Davila does not teach or suggest an integral, unitary catheter tube hub in which the lumen wall is continuous from the distal end to the proximal end, as is recited in the claims.

The Examiner asserts that it would have been obvious to one of ordinary skill in the art to use the teachings of Klump in the hub of Davila in order to prevent the strain relief spring from breaking down the strain relief section. Applicants do not understand precisely what the Examiner is asserting to be the modification to Davila suggested by Klump. Applicants submit that there is no motivation for one of ordinary skill in the art to combine the teachings of Davila and Klump. Klump teaches his nylon strain relief spring as solving the problem of a metallic spring wearing into the insulation around an electrical cable. Davila, however, teach sheath 12 joined to the internal body of hub 14 with spring 15 wound about sheath 12 and coupled to hub 14. See column 3, lines 17-19. The sheath is thus an integral part of the introducer sheath of Davila. Davila teach the spring 15 can be made of stainless steel or nylon. See column 3, lines 32-35. If the Examiner's asserted modification to the Davila device suggested by Klump is that of making the spring coil of nylon, Davila already teach such an element, thus the teachings of Klump appear to be redundant.

If the asserted modification is to make the spaces between the spring coils extend through to the lumen, such a modification would essentially remove the sheath 12 from Davila's device. However, such a modification would render the device unsuitable for its intended purpose. Davila teach the sheath as receiving a catheter. Applicants submit that there is no reason one of ordinary skill in the art would modify the device of Davila according to the teachings of Klump.

Additionally, even if one were to combine the teachings of Davila and Klump, one would not achieve the instant invention, in which the lumen wall is continuous from the helical distal portion through the hub. Neither Davila nor Klump, alone or in combination, teach or suggest the elements of the claims. Withdrawal of the rejection is respectfully requested.

Claim 35 is rejected as being unpatentable over Long in view of Klump. For at least the reasons set forth above, Long fails to teach the basic elements of independent

U.S. Serial No. 09/888,920  
Amendment to Office Action dated December 15, 2004

claim 27, from which claim 35 depends. Klump does not provide what Long lacks, thus the combination of Long and Klump also fails to teach or suggest the elements of claim 35. Withdrawal of the rejection is respectfully requested.

Claims 29, 35, 44, and 45 are rejected as being unpatentable over Davila and Klump as applied to claims 27 and 41, and further in view of Lalikos (US 5,143,409). Claims 36, 37, and 39 are rejected as being unpatentable over Davila and Klump as applied to claim 27, and further in view of Prichard. Davila and Klump, either alone or in combination fail to teach the elements of independent claims 27 and 41 for the reasons set forth above. Neither Lalikos nor Prichard provides what Davila and Klump lack, thus the combinations of Davila, Klump, and Lalikos and Davila, Klump, and Prichard also fail to teach or suggest the claimed invention. Withdrawal of the rejections is respectfully requested.

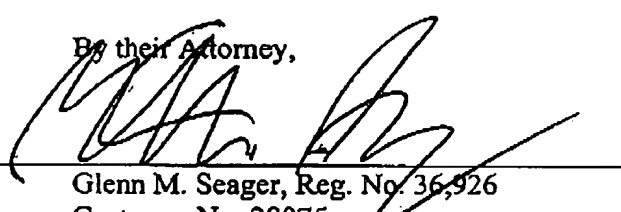
Reexamination and reconsideration are respectfully requested. Any inquiry regarding this matter may be directed to the undersigned representative at (612) 677-9050.

Respectfully submitted,

THOMAS J. HOLMAN ET AL.

By their Attorney,

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Glenn M. Seager, Reg. No. 36,926  
Customer No. 28075  
CROMPTON, SEAGER & TUFTE, LLC  
1221 Nicollet Avenue, Suite 800  
Minneapolis, Minnesota 55403-2420  
Tel: (612) 677-9050